

**REMARKS/ARGUMENTS**

Claims 1 and 19-33 were examined. Claim 1 has been amended. Claims 34-36 have been added. Re-examination and reconsideration of pending claims 1 and 19-36 are respectfully requested.

Rejection under 35 U.S.C. § 102

Claims 1 and 19-25 continue to be rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 4,837,285 issued to Berg et al. This rejection is traversed in part and overcome in part as follows.

In order to expedite prosecution and more clearly claim the present invention, independent claim 1 has been amended to recite an extrudable fragmented biocompatible resorbable hydrogel which is substantially free from a free aqueous phase. Further, the hydrogel has been fragmented by mechanical disruption. These positive recitations have not been reasonably shown or suggested by the cited art.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the .... claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Berg et al. describes collagen matrix beads formed from a network of collagen fibers which are incorporated in wound dressing or implants in the form of a dry powder or in a pharmaceutically acceptable inner carrier. Col. 4, lines 46-48. In particular, these collagen fibers are fashioned into 100-4000 micron beads having an average pore size from 50 to 350 microns, wherein the collagen comprises from 1 to 30% of the volume. Col. 3, lines 20-34. Accordingly, such a large pore size and collagen porosity indicates that any collagen hydrogel of Berg et al. would co-exist with a free aqueous phase within those pores. In other words, the water would be free and not be part of any collagen hydrogel of Berg et al. Further, this free

aqueous phase would comprise 70-99% of the volume based on the collagen porosity recited by Berg et al.

In contrast, claim 1 now clearly requires that the hydrogel of the present invention be free from a free aqueous phase. As noted in the present application on page 8, lines 7-17, page 18, lines 14-16, and Example 8, free water can not be readily expressed from the claimed hydrated hydrogel particles upon compression, filtration, or other mechanical means. This avoidance of free water co-mingling with our hydrogel is due to the fact that the hydrogel particles of the present invention exhibit an average pore size diameter of 500 angstroms (molecular scale porosity), as compared to the macroporous beads of Berg et al. Applicant further point out the distinction that there is an aqueous phase in the hydrogel of the present invention. A hydrogel by definition is gel where the liquid portion is aqueous. The distinction is that the aqueous phase in the hydrogel is not free but rather bound up in the gel.

Further, claim 1 requires that the hydrogel be fragmented by mechanical disruption. The Berg et al. reference fails to show or suggest a fragmented hydrogel, much less fragmentation by mechanical disruption.

Applicants request, if the present rejection is maintained, that the Examiner show or explain where the Berg et al. reference teaches or suggest a fragmented hydrogel by mechanical disruption which is substantially free from a free aqueous phase as presently claimed in claim 1. "Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). Absent such a showing, Applicants respectfully request withdrawal of the 35 U.S.C. § 102 rejection and allowance of independent claim 1 (and dependent claims 19-33).

#### Rejection Under 35 U.S.C. § 103

Claims 1 and 19-25 have also been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Berg et al. Dependent claims 26-33 continue to be rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Berg et al. in view of EP Publication No. 0

493 387 in the name of Hull et al. Such rejections are traversed in part and overcome in part as follows.

Applicants note the present rejection does not establish *prima facie* obviousness under 35 U.S.C. § 103 and M.P.E.P. §§ 2142-2143. Firstly, the Examiner has not established that the prior art references, alone or in combination, teach or suggest all the claim limitations. M.P.E.P. § 2143.03; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974). Secondly, no suggestion or motivation, either in the cited references or in the knowledge generally available to one of ordinary skill in the art, has been cited by the Examiner for the proposed modification of the reference teachings so as to produce the claimed invention. M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

As discussed above with respect to the 35 U.S.C. § 102 rejection, Berg et al. nowhere teaches or suggests a fragmented hydrogel by mechanical disruption which is substantially free from a free aqueous phase as presently claimed in claim 1. Nor has the Examiner pointed to any suggestion or motivation for modifying the teachings of Berg et al. to yield a fragmented hydrogel which is substantially free from a free aqueous phase. Applicants point out that the Examiner bears the initial burden of factually establishing and supporting any *prima facie* conclusion of obviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (CCPA 1976); M.P.E.P. § 2142. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness. *Id.* The Examiner's reliance on Applicants disclosure of mechanical disruption and spray drying is insufficient. Office action, page 4. The teachings, suggestions, and reasonable expectation of success must be found in the prior art, rather than in Applicants disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438 (CAFC 1991). Hindsight reconstruction is not permissible.

Hence, for the several reasons discussed above, Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be removed and that independent claim 1 (and dependent claims 19-33) be allowed. Furthermore, dependent claims 29 through 31 further define the hydrogel as comprising a gelatin, polysaccharide, or a non-biological polymer, respectively. These limitations are nowhere taught or suggested in the Berg et al. patent or Hall et al. reference, alone or in combination. Applicants request, if the present rejection is

maintained, that the Examiner specifically show or explain where these references teach a hydrogel comprising a gelatin, polysaccharide, or a non-biological polymer. See *In re Zurko*, 59 U.S.P.Q.2d 1693 (Fed Cir. 2001) ([I]n a determination of patentability .... the Board cannot simply reach conclusion based on its own understanding or experience - or on its assessment of what would be basic knowledge or common sense. Rather, the Board must point to some concrete evidence in the record in support of these findings). Hence, dependent claims 29-31 further define clearly non-obvious limitations that are further allowable over the cited art of record.

Added Claims

New claims 34-36 have been added. Support for these new claims can be found throughout the originally filed specification. Claims 34-36 are claims 29, 30, and 31 re-written in independent form, respectively. Applicants respectfully request allowance of new claims 34-36.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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